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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,082	07/21/2006	Anton Mayr	BN55-PCT-US	6952

76392 7590 11/06/2008

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
11/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,082	MAYR ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 6, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 70-95 are examined on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 21, 2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 70-95 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

(New Rejection) Claims 70-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "…binary cell culture obtained by cell fusion of two cell types…" does not have support in the

specification since the specification only recites that the binary cell culture is either AVIVER or a permanent cell culture based on CEFs fused with Vero cells, not *any* two cells fused together. Applicant has possession of a species, but not the entire genus claimed.

(New Rejection) Claims 70-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for attenuating myxomavirus through serial passages in CAM, then Vero cells, then AVIVER cells (the binary cell based on CEF fused with Vero) and finally in Vero cells, does not reasonably provide enablement for attenuating myxomavirus through passaging myxomavirus through only one or two of these steps. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

The claimed invention is drawn to methods of attenuating myxomavirus (which may lack certain cytokine receptors, i.e., IFN, TNF or IL) by adapting an isolate from rabbit tissues to replicate in permissive cell systems. This adapted virus can then be serial passaged in binary cell culture (obtained by fusing two cell types together). The virus can initially be adapted by culturing in chorioallantoic membranes of chicken eggs (CAM) and the binary cell culturing step (which may include the binary cell of CEF fused with Vero cells) can then be followed by passaging in Vero cells. However, these variations of methods used in producing a paramunity inducer in the form of an attenuated myxomavirus do not recite the necessary steps for achieving such a product.

For example, the specification recites a one example for obtaining an attenuated myxomavirus by adapting an isolated from a wild rabbit to grow in the CAM of chicken eggs through 3 passages, followed by culturing through 120 passages in Vero cells, followed by 24 passages in AVIVER binary cells (CEFs fused to Vero cells) and lastly the passaging of myxomavirus in Vero cells 300 times. Applicants state on pages 22 and 23 that "After these continuous end-dilution passages, the originally myxomavirus was attenuated." *See pages 22 and 23 of specification.*

In order to attenuate the myxomavirus, particularly one that lacks receptor properties for either an interferon (IFN) receptor, tumor necrosis factor (TNF) and/or interleukin receptor (IL), the following steps are required according to the specification:

(a) isolating a myxomavirus from infected tissue of a rabbit;

(b) adapting the virus to a chorioallantoic membrane (CAM) of an incubated chicken egg;

(c) passaging the adapted virus in Vero cells;

(d) then passaging the Vero cell passaged virus in a binary cell culture obtained by cell fusion between chicken embryo fibroblast (CEF) cells and Vero monkey kidney cells;

(e) followed by passaging the binary cell passaged virus in Vero cells; and

(f) selecting an attenuated myxomavirus that induces paramunity.

-OR-

(f) selecting an attenuated myxomavirus that induces paramunity and has lost receptor properties of one or more myxomavirus interferon receptor, one or more myxomavirus tumor necrosis factor receptor, and one or more myxomavirus interleukin receptor."

Therefore, without performing the method as presented above, additional research is required in order to determine how effective a method based on one or two of the presented steps would be at obtaining an attenuated myxomavirus (as described above).

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

Summary

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648